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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,458	09/19/2003	Harald Wajant	20200/2052	8342

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EXAMINER	
HUMPHREY, DAVID HAROLD	
ART UNIT	**PAPER NUMBER**
1643	

DATE MAILED: 06/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/666,458	WAJANT ET AL.	
	Examiner	Art Unit	
	David Humphrey	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-96* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-96* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-18, 49-67, 72-82, 92-96 in part and claims 19, 21, 68 and 70, drawn to a dsRNA for inhibiting the expression of a cellular FLICE-like inhibitory protein (cFLIP) wherein the complementary strand comprised SEQ ID NO: 2 or SEQ ID NO: 7 and SEQ ID NO: 1, classified in class 536, subclass 23.1.

II. Claims 1-18, 49-67, 72-82, 92-96 in part, and claims 20, 22, 69 and 71, drawn to a dsRNA for inhibiting the expression of a cellular FLICE-like inhibitory protein (cFLIP) wherein the complementary strand comprised SEQ ID NO: 4 or SEQ ID NO: 8 and SEQ ID NO: 3, classified in class 536, subclass 24.5.

III. Claims 23-41, 46-48 in part, and claims 42 and 44, drawn to a method for inhibiting the expression of a cellular FLICE-like inhibitory protein (cFLIP) using a dsRNA wherein the complementary strand comprises SEQ ID NO: 2 or SEQ ID NO: 7 and SEQ ID NO: 1, classified in class 435, subclass 69.2.

IV. Claims 23-41, 46-48 in part, and claims 43 and 45, drawn to a method for inhibiting the expression of a cellular FLICE-like inhibitory protein (cFLIP) using a dsRNA wherein the complementary strand comprises SEQ ID NO: 4 or SEQ ID NO: 8 and SEQ ID NO: 3, classified in class 514, subclass 44.

V. Claims 83-91 in part, drawn to a method for improving the effectiveness of a bioactive substance that induces receptor-mediated endocytosis in a tumor cell which comprises administering a dsRNA wherein the complementary strand comprises SEQ ID NO: 2 or SEQ ID NO: 7, and SEQ ID NO: 1, classified in class 435, subclass 7.2.

VI. Claims 83-91 in part, drawn to a method for improving the effectiveness of a bioactive substance that induces receptor-mediated endocytosis in a tumor cell which comprises administering a dsRNA wherein the complementary strand comprises SEQ ID NO: 2 or SEQ ID NO: 7, and SEQ ID NO: 1, classified in class 435, subclass 69.2.

2. The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P § 806.05 for inventive groups that are directed to different products, restriction is deemed proper because these products constitute patentably distinct inventions for the following reasons. Groups I and II are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. Groups I and II contain patentably distinct double stranded RNA sequences. The RNA of Group I including SEQ ID NOs: 2 and 7 which complementary to SEQ ID NO: 1 is patentably distinct from the RNA of Group II. A

search for the RNA molecule of Group I is not coextensive with the search for the RNA molecule of Group II. Since the RNA molecules of Inventions I and II have different nucleotide sequences, they are patentably distinct.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: the methods of Groups III-VI have different method objectives, different method steps and parameters, and utilize distinct reagents. For example, the methods of Groups III and IV utilize patentably distinct double-stranded RNA molecules to inhibit the expression of cellular FLICE-like inhibitory protein. The methods of Groups V and VI also utilize patentably distinct double-stranded RNA molecules in combination with a bioreactive substance to induce receptor-mediated endocytosis. Bioreactive substances and receptor-mediated endocytosis are not required for the methods of Groups III and IV. A search of all groups would pose an undue search burden on the USPTO's resources due to the fact that the search of one group is not coextensive with the search of any of the other groups. Therefore, the methods of Groups III-VI are patentably distinct.

Inventions I and III, I and V, II and IV, II and VI, are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the

instant case, the double-stranded RNA of Groups I and II can also be used for hybridization assays.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. If Group I, II, V, or VI is elected, Applicant is further required to elect a species for examination purposes. This application contains claims directed to the following patentably distinct species of the claimed invention: Claims 51, 85, 89, and 95, recite tumor necrosis factor (TNF) ligands:

a. TRAMP ligand;

b. CD95 ligand;

c. TNFR-1 ligand; and

d. TNF-related apoptosis-inducing ligand (TRAIL).

Ligands a)- d) are physically and functionally separate and distinct and have different effects. For example, CD95 stimulation of multiple apoptosis-resistant tumor cells by CD95 ligand induces increased motility and invasiveness, a response much less efficiently triggered by TNFα or TRAIL (see Barhart BC et al. EMBO Journal 23: 3175-3185, 2004; in particular, see page 3175, Abstract, lines 4-8).

5. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 49, 50, 53-84, 87, 88, 91, 92, and 93, are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim

is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Humphrey whose telephone number is (571) 272-5544. The examiner can normally be reached on Mon-Fri 8:30AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Humphrey, Ph.D.

May 31, 2006

LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER